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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,534	11/27/2001	Bernhard Homey	DX01342	2027

28008 7590 07/18/2003

DNAX RESEARCH, INC.
LEGAL DEPARTMENT
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[REDACTED] EXAMINER

KEMMERER, ELIZABETH

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 07/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,534	HOMEY ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10 and 13-26 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10, 13, 14 and 16-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 10 and 13-26 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group III (claim 10) and the species of lymphotactin in Paper No. 8 (03 March 2003) is acknowledged.

Applicant's election with traverse of Group I (claims 10, 13, 14 and 16-26) in Paper No. 10 (09 May 2003) is acknowledged. The traversal is on the ground(s) that the claimed invention directed to gene therapy inherently involves delivery of lymphotactin polypeptide, which is the subject matter of the first claimed invention. Applicant concludes that there is no serious burden. This is not found persuasive because therapeutic administration of a polypeptide and therapeutic administration of a nucleic acid are vastly different methods, involving chemically and functionally different active agents (polypeptides versus nucleic acids), methods of delivery, and patient selection. The art must be searched for administration of polypeptide for the first group and nucleic acid for the second group. Art relevant to polypeptide administration would not necessarily disclose gene therapy. Therefore, the searches required for the two groups are non-coextensive, and therefore burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Status of Application, Amendments, And/Or Claims

The preliminary amendment filed 03 March 2003 (Paper No. 8) has been entered in full. Claims 1-9, 11 and 12 are canceled. Claim 15 is withdrawn from consideration. Claims 10, 13, 14 and 16-26 are under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested:
METHODS FOR TREATING WOUNDS COMPRISING ADMINISTRATION OF LYMPHOTACTIN.

Claim Objections

Claim 18 is objected to because of the following informalities: "a chronic ulcera" is improper because "a" indicates singular, whereas "ulcera" is plural. Appropriate correction is required.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10, 13, 14 and 16-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of accelerating wound healing, wherein the wound can be due to various causes and in cutaneous or non-cutaneous tissues, comprising administering lymphotactin (XCL1) to a patient suffering from a wound.

The specification asserts that wounds can be treated by administration of XCL1 (p. 3, last paragraph, for example). No working examples are disclosed wherein XCL1 was administered to a patient or to an *in vitro* model system of wound healing. Although basic methods are disclosed for evaluating a compound's effect on wound healing, no results are reported regarding the effect of XCL1 on wound healing. The specification also does not hypothesize what role XCL1 plays in wound healing (e.g., enhances re-epithelialization, growth factor for fibroblasts, etc.). The art states that XCL1 is a chemoattractant for cytotoxic T lymphocytes (CTL) and natural killer cells (NK) (see Hedrick et al., U.S. Patent 6,022,534; col. 2, li. 17-22). However, the art indicates that this activity is useful for *killing* cells, such as tumor cells (Hedrick et al., *supra*, col. 2, li. 44-54). In fact, the art states that administration of an XCL1 antagonist is desired when it is desired to inhibit cell killing, such as after a transplant (Hedrick et al. *supra*, col. 2, li. 55-65). Therefore, the art teaches against administering XCL1 to enhance cell growth, such as is desirable at a wound.

Chemoattraction of NK and CTL can also be beneficial to a patient to fight off an infection. However, the claims require acceleration of wound healing *per se*, not a method of treating infection at the site of a wound.

Due to the large quantity of experimentation necessary to determine how to administer XCL1 to accelerate wound healing, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the contradictory state of the prior art, the unpredictability of the effects of administering any protein to any patient, and the breadth of the claims which fail to recite limitations regarding the particular effects of administering XCL1, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

